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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,050	09/17/2003	Ru Chih Huang	2240-171278	8071

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EXAMINER	
MARX, IRENE	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 04/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/664,050	HUANG ET AL.	
	Examiner	Art Unit	
	Irene Marx	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) *31-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30 and 39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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The application should be reviewed for errors. Error occurs throughout the specification in the spelling of "nordihydroquaiaretic". The proper spelling is "nordihydroguaiaretic"

The amendment presented fails to comply with 37 C.F.R. 1.173 (b)–(d). Claim 1 is amended without the appropriate indication of brackets or underlining. In claim 1, the formula is presented in the patent. Therefore the underlining is improperly added.

Correction is **required**.

Newly submitted claims 31-38 are directed to inventions that are independent or distinct from the invention originally claimed for the following reasons:

I. Claims 1-30 and 39 drawn to a process of suppressing viral growth by administering a composition comprising various substantially purified compounds, including unidentified and identified derivatives of NDGA, classified in Class 514, subclass 520, for example.

II. Claims 31-38, drawn to chemical compounds, classified in Class 568, subclass 644, for example.

Inventions I and II are related as process of use and product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). In the instant case the product as claimed can be used in materially different process of using that product such as an antioxidant, as an agent to breakdown pre-formed Alzheimer plaque, to activate Ca-dependent K channels in smooth muscle cells and as a lipooxygenase inhibitor.

The inventions above are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches (as indicated by the different classification). The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further, a reference which would anticipate the invention of Group I would not necessarily anticipate or make obvious the other group.

An undue burden would ensue from the examination of multiple compositions and processes which have distinct characteristics and a process of use. Burden lies not only in the search of U.S. patents, but in the search for literature and foreign patents and examination of the

claim language and specification for compliance with the statutes concerning new matter, distinctness and scope of enablement.

For these reasons restriction for examination purposes is proper.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 31-38 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 1-30 and 39 rejected under 35 U.S.C. 251 as being based upon new matter added to the patent for which reissue is sought. The added material which is not supported by the prior patent is as follows:

In the prior patent, no basis or support is found for the compound recited in claims 2 and 20, for example, wherein "N" rather than "NH" is recited and wherein the dot, is practically illegible in claim 2 and in the wrong position. In this regard, the nature of this compound cannot be readily ascertained. Clarification is recommended.

Insertion in the claims of the limitation "are not... . CH_3O- and $CH_3(C=O)O$-, simultaneously" does not have support in the prior patent. The insertion of this limitation is a new concept because it neither has literal support in the prior patent by way of generic disclosure, nor are there specific examples of the newly limited genus which would show possession of the concept of the use of compounds which "are not... . CH_3O- and $CH_3(C=O)O$-, simultaneously". This is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Thus, the insertion of "are not... . CH_3O- and $CH_3(C=O)O$-, simultaneously" is considered to be the insertion of new matter for the above reasons.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-30 and 39 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No basis or support is found in the prior patent for the compound recited in claim 2 and 20, for example, wherein "N" rather than "NH" is recited and wherein the dot, is practically illegible in claim 2 and in the wrong position. In this regard, the nature of this compound cannot be readily ascertained. Clarification is recommended.

Insertion of the limitation "are not... . CH_3O- and $CH_3(C=O)O$-, simultaneously" does not have support in the prior patent. The insertion of this limitation is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited genus which would show possession of the concept of the use of compounds which "are not... . CH_3O- and $CH_3(C=O)O$-, simultaneously". This is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Thus, the insertion of "are not... . CH_3O- and $CH_3(C=O)O$-, simultaneously" is considered to be the insertion of new matter for the above reasons.

Claim Rejections - 35 USC § 112

Claims 1-30 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 15, 16, 18, for example, are confusing in the recitation "wherein the compounds... has "**a** formula". Amendment to --the formula-- would be remedial.

Claim 1 is vague and indefinite in that the "effective viral growth suppressing amount" of the compound to be administered to suppress viral growth is not clearly set forth for any and all compounds, any and all viruses and in any and all modes of administration, even when reading the claims in light of the specification. This is particularly the case with respect to unidentified

compounds having "water soluble substituents". In addition it is unclear that substituents *per se* are "water soluble".

Claims 5-6 and 21-22 are confusing in the recitation "inhibited" with respect to the process. The use of past tense in this context renders the time frame intended unascertainable.

To clarify the invention, it is recommended that the claims be amended to be consistent with respect to reciting either "the compound" or "the substantially purified compound".

Claim 17 is vague, indefinite and confusing since it is uncertain how the therapeutically effective amount of a derivative of NDGA is to be determined in a subject "susceptible to development of resistance to acyclovir" It is uncertain how "susceptibility" is assessed in this context. There is no clear indication of the timing of the administration, determination of susceptibility, or the identity of the "derivative" to be administered.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-30 and 39 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-11 of U.S. Patent No. 5,663,209; and claims 24-32, 34-37 and 40-43 of U.S. Patent No. 6,777,444.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226

(Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Although the conflicting claims are not identical, they are not patentably distinct from each other because at least claim 1 is generic to all that is recited in claims 2-11 U.S. Patent No. 5,663,209, respectively, claims 24-32, 34-37 and 40-43 of U.S. Patent No. 6,777,444.

Claims 1-30 and 39 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 7, and 12-14 of U.S. Patent No. 6,214,874 and claims 1-9 of U.S. Patent No. 6,417,234 each in view of Shantha (U.S. Patent No. 5,195,965).

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Although the conflicting claims are not identical, they are not patentably distinct from each other because they are directed to substantially the same method of suppressing the growth of a virus using the same composition(s). A method of suppressing the growth of a human papilloma virus (HPV) or inhibiting replication of HPV in an HPV-induced tumor with substantially the same compounds as herein would have been obvious to one of ordinary skill in the art at the time the claimed invention in view of the invention claimed in each of the cited patents because of the teachings of Shantha *et al.* which adequately demonstrate that HPV is involved in the pathology of tumors at least in the cervix and also in cervical cancer. Therefore suppression of viral growth for the purpose of treating virally induced tumors wherein viral particles are growing and replicating would have been obvious to one of ordinary skill in the art at the time the claimed invention was made.

Therefore, the claims in the conflicting applications render the instant method of suppressing the growth of a virus using nordihydroguaiaretic acid derivatives obvious to one of ordinary skill in the art.

Therefore the claims are co-extensive.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5-6, 15-18, and 21-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Jordan (U.S. Patent No.4,880,637) in light of Orth *et al.* (U.S. Patent No. 5,342,930)

The claims are directed to a method for suppressing viral growth in a host infected with a virus or inhibiting replication of a virus that is resistant to or susceptible to development of resistance to acyclovir comprising the steps of administering a therapeutically effective amount of a derivative, including a water soluble derivative, of NDGA to a subject.

Jordan is directed to a method of treatment of a subject infected with a virus comprising the steps of administering a therapeutically effective amount of an NDGA derivative, which may be a water soluble derivative, to a subject. See, e.g., Table 7 for the administration of NDGA tetrapropionate, which is presumed to be a water soluble substituent. In addition the complexes of NDGA with zinc chloride or with zinc gluconate are deemed to constitute NDGA derivatives.

The suppression of viral growth or viral replication at least to same extent is an inherent property of the compounds. That the papilloma viruses are resistant or susceptible to developing resistance to acyclovir can reasonably be presumed, since acyclovir is not generally effective in the treatment of such viral infections.

Orth *et al.* is cited as evidence that viruses, such as papilloma viruses, are involved in various skin tumors and in hyperplasias capable of degenerating into intra-epithelial neoplasias and cutaneous cancers. Among papillomavirus involved in cancers can be mentioned intra-epithelial neoplasias, cutaneous cancers, the cancers of the epidermodysplasia verruciformis genital neoplasias and cancers of the uterine cervix, condylomas and papillomas. See, e.g., col. 10, lines 57-65.

Therefore, the claims are anticipated by the reference.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Irene Marx
Primary Examiner
Art Unit 1651